The latest trends in clinical research were examined at a conference held at the Minneapolis Convention Center on October 4-5. More than 600 participants attended “Current Issues in Clinical Research,” sponsored jointly by the University’s Academic Health Center and Mayo Clinical Trial Services. Focusing on emerging trends, the conference provided a comprehensive review of clinical research performance, led by nationally prominent faculty. The following is a brief look at a selection of topics.

Barbara Alving, M.D., acting director of the NIH’s National Center for Research Resources, addressed the NIH Roadmap for Re-engineering Clinical Research. To build the research infrastructure, the NIH is promoting clinical research informatics and integrating clinical research networks to more effectively conduct clinical studies and trials. For instance, informatics will standardize functions while... (continued on page 2)

The health and life expectancy of Minnesotans consistently rank number one in the nation—a standard that, unfortunately, is not shared across the state’s diverse populations. Ethnic and racial minorities including African Americans, Asians, Latinos, and American Indians continue to experience poorer health and disproportionately higher rates of illness, such as diabetes, cancer, and heart disease, as well as shorter life spans.

Several new initiatives sponsored by the Office of Clinical Research are aimed at eliminating health disparities. For instance, building on current relationships, the Office of Clinical Research has formed a working group of more than 150 members from the University and community. By forming relationships across disciplines and communities, participants are able to learn from each other and collaborate on meaningful efforts to reduce health disparities. For more information, go to: http://www.ahc.umn.edu/ocr/partner/hlthdisp.html.

In addition, the Medical School initiated the Program in Health Disparities Research, led by Kolawole S. Okuyemi, M.D., M.P.H. This program’s mission is to develop, coordinate, conduct, and disseminate interdisciplinary research, education, and community partnership initiatives aimed at reducing and ultimately eliminating health disparities. Currently, the program supports four faculty and one postdoctoral fellow conducting health disparities research in areas such as smoking cessation, obesity, physical activity, diabetes, peripheral arterial disease, acculturation, social support, and health communication. (continued on page 2)


**Director’s Update, continued.**
To ensure that community needs are being addressed, we have convened a Health Disparities Advisory Board. The board consists of community leaders in a variety of fields, providing important guidance and feedback for current and future research in health disparities. For instance, they are helping us shape a Request For Applications for collaborative seed grants, sponsored by the Office of Clinical Research and Program in Health Disparities Research. We expect to announce the RFA in December 2006.

We are also offering a quarterly seminar, the Distinguished Visiting Scholars Series in Health Disparities. This series brings an acknowledged leader in health disparities research to the University to present lectures and meet in small groups with faculty, fellows, and students, and visit community organizations. The first scholar, Spero M. Manson, Ph.D., head of the American Indian and Native Alaska Programs at the University of Colorado Health Sciences Center, presents his talk “Wounded Spirits, Ailing Hearts” on Oct 3rd and will visit the Indian Health Board of Minneapolis.

Through these initiatives, and others to come, we are working with community organizations and clinical researchers to improve the health for all populations.

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**Current Issues in Clinical Research, continued.**

reducing impediments, interlink AHCs with clinical trial networks, and allow for system-to-system communication for monitoring and reporting.

Ethicist Jeremy Sugarman, M.D., M.P.H., M.A., Johns Hopkins University, discussed **ethical issues related to research** involving special populations. He noted that over the years, ethics pertaining to the enrollment of special populations in research has moved from a focus on protection to that of access. Although updated regulations have begun to address issues surrounding protection vs. access, the concept of “justice” for participants must be considered at every step of the research process. One suggestion is to involve community consultation in clinical research.

President and C.E.O. of BG Medicine, Inc., Pieter Muntendam, M.D., addressed **developments in genomics, proteomics, and metabolomics.** Drug development has relied on phenotypical observations that are based on limited focused measurements. Increasingly, this is being replaced by a molecular-based paradigm, an integrated approach that studies the effects of drugs on biological systems; for instance, identifying early response biomarkers to predict a drug’s effect.

This conference will be offered annually.

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**News**

**Breakfast mentoring club introduced.** A monthly informal breakfast meeting, led by OCR Executive Director Jasjit Ahluwalia, M.D., M.P.H., M.S., will be held for interested AHC junior faculty, fellows, and scholars. The purpose is to share support and perspectives on conducting clinical research. Though open to all who are interested, each session will be limited to 5 mentees. Days, times, and locations will vary to accommodate different schedules. To express interest, please contact Meredith Craven at mcraven@umn.edu or (612) 626-6033.

**Report on drug safety released by Institute of Medicine (IOM).**

“The Future of Drug Safety: Promoting and Protecting the Health of the Public” contains 25 recommendations. They include: labeling requirements and advertising limits for new medications; clarified authority and additional enforcement tools for the FDA; clarification of FDA’s role in gathering and communicating additional information on marketed products’ risks and benefits; and, mandatory registration of clinical trial results to facilitate public access to drug safety information. For further information, go to http://www.iom.edu/CMS/3793/26341/37329.aspx.

*(more News on page 3)*
Like many investigators, Ajay Israni’s research is often informed by his clinical work. A nephrologist, Israni couldn’t help notice that African American patients whom had undergone kidney transplantation tended to have worse outcomes than their white counterparts. In particular, he noted that African Americans suffer a substantially greater rate of allograft loss.

“Health disparities is a complex issue,” says Israni, who believed that such disparities in outcome “could not be completely explained by immunological differences and socioeconomic factors.” As a starting point, Israni suspected that nonadherence to immunosuppressive medication may partly explain the disparate outcomes. In 2005, using microelectronic cap monitors to track medication use, Israni confirmed that African Americans had lower adherence to medication than whites; however, the discrepancy decreased substantially after adjusting for variations in transplant center care and dosing frequency of medication. That is, more frequent dosing schedules were associated with decreased adherence and partly explained the lower adherence observed among African Americans. Also affecting adherence rates were center-related characteristics, though characteristics such as staffing levels, “cultural competency” of care providers, patient satisfaction with the patient-provider relationship, and the frequency and quality of patient contact with providers are difficult to assess.

Dr. Israni’s recent findings uncovered a high degree of variability in follow-up care nationally after kidney transplantation. In the face of such variation, Israni realized that evidence-based guidelines for appropriate care following kidney transplantation were lacking. In particular, additional studies are needed to investigate the center-related characteristics that influence adherence and long-term outcomes.

Next, Israni hopes to examine differences in follow-up care, such as number of appointments and types of diagnostic testing, by utilizing claims data in a national registry of all end-stage renal disease patients. This registry is held at HCMC, where Israni is an attending physician. He is hopeful that this approach to healthcare disparities research “will not only lead to understanding the impact of process of care post-transplantation on the poor outcomes in African Americans, but to important improvements in access to care among patients with chronic health conditions in the U.S.”
The United States is seeing an alarming increase in the prevalence of obesity and type 2 diabetes in children. Also rising, particularly among obese adolescents, is the prevalence of metabolic syndrome, characterized by dyslipidemia, abdominal obesity, hypertension, and impaired glucose tolerance. These conditions may be associated with multiple cardiovascular risk factors and atherosclerosis—a relationship which Lisa Chow, M.D., is investigating with hopes for better treatment and prevention. Chow is a scholar in CAPS, the Career Advancement Program for Clinical Research Scholars, an NIH-funded K12 program.

As an assistant professor of medicine in the Division of Diabetes, Endocrinology, and Metabolism in the Medical School’s Department of Medicine, Chow’s research focuses on defining the influence of obesity, metabolic syndrome, and insulin resistance on cardiovascular risk factors in young adults. As a CAPS scholar, Chow has been allocated 80 percent protected time to conduct research, working closely with three mentors: Elizabeth Seaquist, M.D., professor, Department of Medicine, Medical School; Michael Garwood, M.D., professor, Department of Radiology, Medical School; and Lynn Eberly, Ph.D., associate professor, Division of Biostatistics, School of Public Health.

As skeletal muscle is the largest utilizer of glucose in the body, Chow is interested in the effects of dysfunction in skeletal muscle metabolism and how this may contribute to insulin resistance. To do this, Chow will work with Garwood using a new, non-invasive procedure involving magnetic resonance spectroscopy (MRS) to measure muscle metabolism in vivo. She will compare the results of this method with results obtained from standard needle biopsies. The goal is to have a better understanding on the cause of insulin resistance, the skeletal muscle effects of various therapies (such as diet and exercise) which improve insulin resistance, and ultimately, to develop new therapies which will improve insulin resistance.

Given the growing epidemic of obesity, diabetes, and the metabolic syndrome, of which insulin resistance is a major component, Chow hopes that this knowledge will help alleviate, if not prevent, the complications associated with these chronic conditions.

For more information on CAPS, go to: www.epi.umn.edu/CAPS